UNITED STATES DISTRICT COURT
FOR THE
DISTRICT OF VERMONT

JONATHAN A. BLOOM,

Plaintiff,

v.

SYLVIA BURWELL, in her official capacity as Secretary, United States Department of Health and Human Services,

Defendant.

Case No. 5:16-cv-121

OPINION AND ORDER
(Doc. 9)

Plaintiff Dr. Jonathan A. Bloom brings this action under 42 U.S.C. §§ 405(g) and 1395ff(b)(1)(A), seeking judicial review of two separate decisions by the Medicare Appeals Council ("MAC") denying his request for Medicare payment of claims relating to a continuous glucose monitor ("CGM"), which he asserts is the "standard of care" for individuals who, like himself, suffer from "brittle" diabetes.[1] (*See* Doc. 1; *see also* Docs. 1-1; 1-2 (unfavorable MAC decisions).) The Secretary has filed a Motion for Remand under the sixth sentence of § 405(g), asserting that there is "good cause" for remand. After hearing argument on September 29, 2016, the court ordered the Secretary to file a certified copy of the administrative record so that the court could evaluate the Secretary's contention that the record is insufficient to determine whether a CGM qualifies as "durable medical equipment" covered by Medicare under 42 U.S.C. §§ 1395k(a)(1), 1395x(n), 1395x(s)(6), and 42 C.F.R. § 414.202. (*See* Doc. 17.) The Secretary filed the administrative record on December 16, 2016. (*See* Doc. 18.)

[1] "Brittle" diabetes is a form of diabetes "in which there are marked fluctuations in blood glucose concentrations that are difficult to control." *Stedman's Medical Dictionary* 243150 (28th ed. 2006) (Westlaw).

Background

The administrative record includes the MAC and Administrative Law Judge (ALJ) files from the relevant administrative proceedings, as well as transcripts of the separate March 31, 2015 hearings before ALJ Pere J. Jarboe (AR 376–95) and ALJ Charles W. Dorman (AR 402–06), and the June 16, 2015 hearing before ALJ Bennett Engelman (Supp. AR 4–14). ALJ Jarboe and ALJ Dorman issued unfavorable decisions (AR 89–94, 260–70), which the MAC ultimately adopted (Doc. 1-1). ALJ Engelman issued a favorable decision (Supp. AR 38–46), which the MAC ultimately reversed (Doc. 1-2). Dr. Bloom represented himself at each of the ALJ hearings.

The record includes the following facts about Dr. Bloom's CGM system and how he uses it.[2] Dr. Bloom has been using continuous glucose monitoring since 2006. (*See* AR 43, 45, 381, 384, 403; Supp. AR 5.) He currently uses a Medtronic MiniMed Paradigm Revel insulin pump with continuous glucose monitoring. (AR 45, 63; Supp. AR 10.) The FDA approved MiniMed's Continuous Glucose Monitoring System on June 15, 1999. FDA, Approval Order, http://www.accessdata.fda.gov/cdrh_docs/pdf/P980022A.pdf [hereinafter "Approval Order"].[3] The 1999 Approval Order has been supplemented numerous times since then, including approvals for later generations of the system marketed under the Paradigm Revel trade name. *See* FDA, Premarket Approval, http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P980022 (listing supplements). The system is prescribed by Dr. Bloom's treating physician, and the prescription has to be renewed annually. (Supp. AR 12.)

[2] In a few instances, the court also refers to documents subject to judicial notice. The most relevant facts for present purposes, however, concern how Dr. Bloom uses the CGM system, since the MAC's decision in both appeals was based on its conclusion that the CGM system is not used for a "primary medical purpose." (Doc. 1-1 at 11; Doc. 1-2 at 12.)

[3] The court may take judicial notice of FDA publications available on its website. *See* Fed. R. Evid. 201; *Sekisui Am. Corp. v. Hart*, 15 F. Supp. 3d 359, 363 n.29 (S.D.N.Y. 2014).

Dr. Bloom's CGM system consists of a sensor, a transmitter, and a monitor. The user injects the sensor with a needle, and after the needle is removed the sensor is connected to the wireless transmitter. (*See* AR 379.) The sensor does not directly measure blood sugar, but supplies information that amounts to a "guide to what your blood sugar would be." (Supp. AR 12.)[4] The transmitter sends the sensor's readings to the monitor and also to an insulin pump, which is integrated with Dr. Bloom's CGM system. (*See* AR 379–80.)

The sensors have a limited lifespan and are not reusable; when a patient is done using a sensor, it is taken out and thrown away. (AR 391.) Dr. Bloom orders sensors for his CGM system once a month or once every three months. (AR 385.) Each sensor lasts about six days, so five sensors last about a month. (AR 386, 391.) As of 2015, Dr. Bloom paid about $470 for a set of five sensors. (AR 386; *see also* Supp. AR 8.)

The transmitter is an external device that is connected to the sensor. As of June 2014, Minimed Distribution Corporation charged $659 for the transmitter component of the CGM system. (*See* AR 316.) The monitor displays the data collected from the sensor and has hypoglycemic alarms that allow Dr. Bloom to "detect, check and treat impending hypoglycemia, particularly when it occurs during sleep." (AR 43–44.) When he is wearing his CGM system, Dr. Bloom receives "reliable alarms and is able to react appropriately." (AR 47.)

In addition to his continuous glucose monitoring, Dr. Bloom manually checks his blood sugar between five and fifteen times per day. (AR 45; *see also* AR 47, AR 380.) At a September 2008 consultation—after Dr. Bloom had been referred to him—Dr. Richard Pratley noted that Dr. Bloom's fingers showed "evidence of frequent glucose monitoring." (AR 46.)

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[4] According to the 1999 Approval Order, the sensor measures "interstitial glucose levels." Approval Order at 1. Interstitial fluid (also called tissue fluid) is "the fluid in spaces between the tissue cells, constituting about 16% of the weight of the body; closely similar in composition to lymph." Stedman's Medical Dictionary 341120 (28th ed. 2006) (Westlaw).

Dr. Bloom enters the results of his manual blood sugar checks into his CGM system. (AR 47.) According to Dr. Bloom's testimony, he continues to manually check his blood sugar because the CGM system is only a "guide to what your blood sugar would be, it's not an absolute." (Supp. AR 12.) According to Dr. Bloom, "[t]here are times when your blood sugar is different from what the sensor tells you, but that's when you change your sensor and put a new one in that's more accurate." (*Id.*)

According to Dr. Pratley, despite Dr. Bloom's "scrupulous glycemic control," the fact that Dr. Bloom is "well versed in self care and management," and Dr. Bloom's "self monitoring of blood glucose," he still has "markedly labile blood sugars with frequent hypoglycemia." (AR 43.) Dr. Bloom has "severe hypoglycemic unawareness," which makes it impossible for him to detect when he is experiencing an unexpected low. (*Id.*) That has resulted in hospitalization and other instances in which he was in "substantial jeopardy." (*Id.*) According to Dr. Pratley, Dr. Bloom's use of a CGM system "has markedly improved his management, quality of life and overall safety." (AR 44.) Also according to Dr. Pratley, the CGM system "has provided a clinically significant benefit in terms of [Dr. Bloom's] diabetes management and especially with respect to the avoidance of hypoglycemia." (*Id.*)

Analysis

Under the sixth sentence of 42 U.S.C. § 405(g), the Secretary may move for a remand before filing an answer, and upon such a motion the court may remand the case "for good cause shown." 42 U.S.C. § 405(g).[5] Here, the Secretary seeks a sentence-six remand, arguing that "the administrative record lacks evidence pertaining to the functionality of a CGM system and

[5] There are two types of sentence-six remands: "(1) remands for good cause which do not require additional evidence; and (2) remands for the purpose of taking new evidence, but only upon a showing of good cause." *Longey v. Sullivan*, 812 F. Supp. 453, 456 n.3 (D. Vt. 1993).

whether it qualifies as [durable medical equipment]." (Doc. 9 at 13.) According to the Secretary, "the administrative record as a whole lacks substantive information concerning the functionality of a CGM, including its functionality in conjunction with or in comparison to a traditional blood glucose monitor." (*Id.*) Dr. Bloom faults the Secretary for not articulating what evidence (if any) is missing from the administrative record that might warrant a remand. (*See* Doc. 10 at 8.) According to Dr. Bloom, neither of the MAC decisions at issue can be cured by a remand. (*See id.* at 9.)

The court has reviewed the administrative record to evaluate the quantity and quality of evidence it contains bearing on whether Dr. Bloom's CGM system meets the definition of "durable medical equipment." The applicable regulations define "durable medical equipment" to mean equipment that (1) "[c]an withstand repeated use"; (2) "[i]s primarily and customarily used to serve a medical purpose"; (3) is generally "not useful to an individual in the absence of an illness or injury"; and (4) is "appropriate for use in the home." 42 C.F.R. § 414.202. In both of the MAC decisions from which Dr. Bloom has appealed, the MAC concluded that the second element was not satisfied. (*See* Doc. 1-1 at 11; Doc. 1-2 at 12.) The court finds that the administrative record is sufficient for the court to evaluate whether "substantial evidence" supports the Secretary's determination that Dr. Bloom's CGM system is not "primarily and customarily used to serve a medical purpose."

The Secretary contends that a remand would be consistent with two court decisions regarding CGM systems where, according to the Secretary, the administrative record was similarly lacking in evidence bearing on whether a CGM system qualifies as durable medical equipment: *Finigan v. Burwell*, No. 15-12246-WGY, 2016 WL 2930905 (D. Mass. May 19, 2016), and *Whitcomb v. Burwell*, No. 13-CV-990, 2015 WL 3397697 (E.D. Wis. May 26, 2015).

(*See* Doc. 9 at 14–15; Doc. 11 at 5.) The courts in each of those cases remanded after concluding that the MAC had improperly given deference to a policy article. *See Finigan*, 2016 WL 2930905, at *6 (according "substantial deference" to policy article was legal error); *Whitcomb*, 2015 WL 3397697, at *4 (policy article was not entitled to substantial deference; remanding to permit the Secretary to apply the proper legal standard). But *Finigan* and *Whitcomb* do not support the Secretary's position regarding sufficiency of the administrative record; the remands were ordered in those cases because of legal error regarding the weight given to policy articles.[6]

The Secretary says that she "acknowledges the outcomes" in *Finigan* and *Whitcomb*, and that "rather than pursuing litigation that is likely to result in a remand for further proceedings, asks this Court to remand the case before answer." (Doc. 11 at 5.) In a prior order, the court found the issue of weight given to Policy Article A33614 was not likely to be "good cause" for a sentence-six remand because the Secretary had not actually conceded that the weight given was legal error. (*See* Doc. 17 at 2.) The court continues to hold that "good cause" for a sentence-six remand is lacking in this case.

Here, unlike in *Finigan* and *Whitcomb*, the MAC did not actually say that it was giving the policy article "substantial deference." The Secretary concedes as much. (Doc. 9 at 12; *see also* Doc. 11 at 3.) What the MAC did do was to state that it had "[h]istorically" given substantial deference to policy articles (Doc. 1-1 at 10; Doc. 1-2 at 10); to discuss Policy Article A33614; and to ultimately agree with the article's conclusion that CGMs are "precautionary." (Doc. 1-1 at 11; Doc. 1-2 at 11–12). Therefore, the Secretary's discussion of the weight the

[6] In *Finigan*, the MAC had stated that the record was "insufficient to depart from the coverage standards" articulated in Policy Article A33614. *Finigan*, 2016 WL 2930905, at *6. But according to the court, the MAC "did not explain what more would have rendered the record sufficient." *Id.* at *4. The court did not expressly analyze the sufficiency of the record because the MAC's assertion about insufficient evidence incorporated a "false premise": that the policy article was entitled to substantial deference. *Id.* at *6.

MAC afforded to the policy article was necessarily hedged; the Secretary could not acknowledge that "substantial deference" was in fact erroneously given because it is unclear from the record whether that is so.

The Secretary does acknowledge that affording "substantial deference" to a policy article is legal error. (Doc. 11 at 4.) Generally, when it is not clear from the record whether the decision-maker below applied the wrong standard, the proper course is to vacate and remand. *Cf. Manzur v. U.S. Dep't of Homeland Sec.*, 494 F.3d 281, 289 (2d Cir. 2007) ("This Court also will not hesitate to vacate and remand where the BIA or IJ analysis is insufficient to determine whether the correct legal standard was applied."); *United States v. Adlman*, 134 F.3d 1194, 1203 (2d Cir. 1998) (vacating and remanding where it was unclear what standard the district court used to find the work-product doctrine inapplicable); *Schaal v. Apfel*, 134 F.3d 496, 505 (2d Cir. 1998) (vacating and remanding in social security disability appeal, partly because court was unable to determine what legal standard ALJ applied in weighing physician's opinion).

But there is an exception where "application of the correct legal standard could lead to only one conclusion." *Schaal*, 134 F.3d at 504; *see also Johnson v. Bowen*, 817 F.2d 983, 986 (2d Cir. 1987) ("[W]here application of the correct legal principles to the record could lead to only one conclusion, there is no need to require agency reconsideration."). Dr. Bloom's position appears to be that this case fits the exception. (*See* Doc. 10 at 10 ("[A] remand will not 'cure' the improper deference to the Article to the extent the decisions rely on it.").) The court concludes that Dr. Bloom is entitled to an Answer from the Secretary, and to test whether this is such an exceptional case.

The court is mindful of Dr. Bloom's concerns about delay—one reason he opposes remand in this case is because he views the administrative process as likely to result in excessive

delay. (*See* Doc. 10 at 11.) The court in *Finigan* expressed similar concern.[7] If the court ultimately determines that remand is necessary, this court case would probably seem to be only one more source of delay. By objecting to the Secretary's Motion for Remand, however, Dr. Bloom has signaled his willingness to accept that possibility in exchange for judicial review on the existing factual record developed through the administrative process. Since the court agrees with Dr. Bloom that this record is substantial and may provide a basis for a ruling on the merits in one direction or the other, the court will deny the request for a sentence-six remand and proceed with the appeal.

Conclusion

The Secretary's Motion to Remand (Doc. 9) is DENIED.

Dated at Rutland, in the District of Vermont, this 17 day of January, 2017.

Geoffrey W. Crawford, Judge
United States District Court

[7] In that case, the court stated:

> By the Court's count, it will be at least the sixth decision-maker to weigh in on this coverage issue. And, because of the relief ordered . . . , it unfortunately will not be the last. Is this too much process? Would those like Finigan be better off with fewer levels of review, but with more resources dedicated to each level? These are important questions obviously outside the scope of this decision and the Court's power, but that are raised every time the Court details a Social Security petitioner's bureaucratic appeals-on-appeals path to the Court. The Court has previously lamented the myriad delays faced by claimants.

Finigan, 2016 WL 2930905, at *2 n.2.